

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Nelson et al.  
Filed: Simultaneously Herewith  
Serial No.:  
For: Mass Spectrometric Immunoassay  
Atty. Docket No.: 530-013

Box Fee Amendment  
Assistant Commissioner for Patents  
Washington, D.C. 20231

## Preliminary Amendment

Dear Sir:

Prior to examination of the above-specified application, kindly amend the subject application as follows:

## AMENDMENTS

### In the Specification:

As the first paragraph, please insert the following paragraph:

This application is a continuation of pending application serial no. 09/024,988  
filed on 02/17/98, which was a continuation of original application serial no.  
08/449,903, which was filed on 5/23/95, now abandoned.

### In the Claims:

Please cancel pending claims 31, 33, 40 and 41.

Please include the following new claims:

48 A method for determining whether a specimen contains a certain analyte species, comprising the steps of:

a. capturing and isolating the certain analyte species from the specimen, said step of capturing and isolating involving the use of an affinity reagent having a specific affinity for the certain analyte species;

- b. detecting the presence of the isolated one or more certain analyte species through the use of a mass spectrometer to determine whether each of the one or more certain analyte species was present in the specimen; and
- c. determining the identity of the one or more certain analyte species via molecular weight analysis.

54 The method of claim 53, further including the steps of:

- a. immobilizing an antibody onto a solid substrate to produce said affinity reagent;
- b. combining an effective amount of the affinity reagent with the specimen until the affinity reagent binds with each of the one or more certain analyte species that is present in the specimen to produce a post-combination affinity reagent and an unbound remainder;
- c. separating the post-combination affinity reagent from the unbound remainder to form an isolated post-combination affinity reagent;
- d. adding a laser desorption/ionization agent to the isolated post-combination affinity reagent to form a mass spectrometric mixture; and
- e. mass spectrometrically analyzing the mass spectrometric mixture to produce a mass spectrum, said mass spectrum indicating whether the specimen contained each of the one or more certain analyte species by exhibiting a mass spectrometric response located at the unique mass-to-charge ratio of each of the certain analyte species.

55 The method of claim 54 wherein the step of combining an effective amount of the affinity reagent with the specimen is accomplished using micropipette tip in which there is a filter element to which the affinity reagent is bound.

56 The method of claim 54 further including the step of adding a disassociation agent to the isolated post-combination affinity reagent prior to the step of adding the laser desorption/ionization agent.

57 The method of claim 56 wherein the step of combining an effective amount of the affinity reagent with the specimen is accomplished using micropipette tip in which there is a filter element to which the affinity reagent is bound.

58 The method of claim 53, further including the steps of:

- a. immobilizing a plurality of antibodies onto a solid substrate to produce said affinity reagent;
- b. combining an effective amount of the affinity reagent with the specimen until the affinity reagent binds with each of the one or more certain analyte species that is

present in the specimen to produce a post-combination affinity reagent and an unbound remainder;

c. separating the post-combination affinity reagent from the unbound remainder to form an isolated post-combination affinity reagent;

d. adding a laser desorption/ionization agent to the isolated post-combination affinity reagent to form a mass spectrometric mixture; and

e. mass spectrometrically analyzing the mass spectrometric mixture to produce a mass spectrum, said mass spectrum indicating whether the specimen contained each of the one or more certain analyte species by exhibiting a mass spectrometric response located at the unique mass-to-charge ratio of each of the certain analyte species.

- 59 The method of claim 58 wherein the step of combining an effective amount of the affinity reagent with the specimen is accomplished using micropipette tip in which there is a filter element to which the affinity reagent is bound.
- 60 The method of claim 58 further including the step of adding a disassociation agent to the isolated post-combination affinity reagent prior to the step of adding the laser desorption/ionization agent.
- 61 The method of claim 60 wherein the step of combining an effective amount of the affinity reagent with the specimen is accomplished using micropipette tip in which there is a filter element to which the affinity reagent is bound.

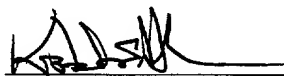
#### REMARKS

##### *Claim Status*

Claims 31, 33, 40 and 41 are pending. Claims 31, 33, 40 and 41 have been canceled above. New claims 48-60 have been added. Therefore, claims 48-60 are now pending.

Respectfully submitted,

Date: 3/14/06



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